DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

LAP Surgical Systems, LLC
Donald Wenner, M.D.
100 North Pennsylvania
Roswell, NM 88203

JUL 27 2015

Re: K022686
Trade/Device Name: Lap Surgical Systems Multiple Instrument Guide
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED, GCJ, FBN
Dated (Date on orig SE ltr): November 14, 2002
Received (Date on orig SE ltr): November 14, 2002

Dear Dr. Wenner,

This letter corrects our substantially equivalent letter of November 25, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K022686

STATEMENT OF INDICATIONS FOR USE

The Multiple Instrument Guide (MIG) is used for surgical instrument and choledochoscope access into the common bile duct during laparoscopic common bile duct exploration (LCBDE).

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022686

K022686

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July 16th, 2002

510 (k) SUMMARY

The following is the 510 (k) Summary as required by section 807.92 (c), prepared on the 8th day of July, 2002. This summary is in reference to the 510(k) submission for the proposed marketing of Lap Surgical's Multiple Instrument Guide. The common or usual name for the Multiple Instrument Guide is the "MIG", and the classification name of the device is Catheter, Biliary, Diagnostic.

In regards to substantial equivalence, the MIG will be claiming equivalence to the Class II Laparoscopic Cholangiography Catheter marketed by Arrow International, Inc.

The Multiple Instrument Guide ("MIG") is a three-lumen plastic extension that has a curved J-tip configuration. The MIG in its entirety is 13 inches in length. The largest lumen is 3.4mm in diameter and will allow the passage of a choledochoscope through it. The other two lumens are 1.8mm and 2.0mm in diameter. The MIG itself is composed entirely of polyethylene. The sheath which aids the introduction of the MIG into the patient is composed of a clear rigid, non-toxic vinyl compound developed especially for the medical industry. The sheath is 8.0 inches in length, a hollow end diameter of .320 inches, and a wall thickness of .035 inches. It is a simple hollow tube in which the MIG is passed through, into the patient. The MIG is also accompanied by a small plug (which does not come into contact with the patient) to prevent leaking of the carbon dioxide used in laparoscopic procedures. The plug is composed of polyethylene, is .069 inches in diameter, and is 1.5 inches long. The MIG requires no form of electrical or battery power, it is operated manually by a laparoscopic surgeon. The MIG, sheath, and plug are all sterile, single use items. The MIG is coated with a Hydromer, Inc. hydrophilic coating which becomes lubricious when activated with water. Its purpose is to reduce friction when the MIG enters the sheath and the patient. The coating is a completely inert, non-leeching, non-extractable material. It alleviates the need for the physician to use other water-based lubricants, because it is permanently coated onto each MIG. This same

Hydromer, Inc. coating is used on many other, already marketed devices. A list of these other devices with Hydromer coating is appended in Attachment 5.

The MIG is used during the performance of lower common bile duct exploration (LCBDE). It is used to introduce a video choledochoscope into the common bile duct (CBD), and to deploy various catheters and tools into the CBD to clear the biliary system of stones and to inspect the bile ducts and ampulla of Vater to obtain biopsy material. Balloon catheters, irrigation catheters, stone baskets, biopsy forceps, or papillotome are among the various tools that can be deployed alongside a choledochoscope through the MIG. By using the MIG, most cases of choledocholithiasis (the presence of stones in the CBD) can be successfully treated, even in the more difficult cases. In addition, the MIG serves as protection to the ultra thin choledochoscope, and allows it to be safely, and easily deployed into the CBD and manipulated.

The MIG and its predicate device to which we are claiming substantial equivalence are very similar in their functions, as well as their technological characteristics. The Multiple Instrument Guide by Lap Surgical Systems, Inc. and the cholangiocatheter by Arrow, Inc. are both used to explore the biliary systems of the patients in procedure. Both devices ultimately serve as a tool to identify any ductal stones or other anomalies that pose serious health risk to the patient, and further enable the surgeon to remove these potential hazards. The key difference in use is that the MIG is introduced into the patient via the common bile duct where as the cholangiocatheter is introduced via the cystic duct. However, they both end up exploring the same anatomical sites of the patient. The cholangiocatheter actually comes with a latex balloon catheter, whereas the MIG does not. This alleviates any possible reactions to a latex product from the MIG or its accessories. The MIG is composed entirely of polyethylene, as the cholangiocatheter is composed of polyurethane. The MIG is introduced into the abdominal cavity with a clear, rigid, non-toxic vinyl compound made especially for the medical field while the cholangiocatheter is introduced through a stainless steel sheath. Not only do the devices serve the same resulting benefits to the patients, but also they are both sterile, single use devices that are used during a laparoscopic procedure in the operating room. Neither device employs any type of electricity, or relies on internal moving parts. Both devices are reliant solely on the expertise of surgeons skilled in advanced laparoscopic procedures.